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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके
Separate paging is given to this Part in order that it may be filed as a separate compilation

MINISTRY OF PETROLEUM AND CHEMICALS AND MINES AND METALS

(Department of Petroleum and Chemicals)

RESOLUTION

New Delhi, the 30th April 1970

No. 3(52)/68-CH.III.—The Government requested the Tariff Commission in August, 1966 to examine the cost structure of 18 essential drugs and make recommendations about their prices and some other related matters (*vide* former Ministry of Commerce letter No. 20(3)-Tar./66, dated the 25th August 1966). The Commission conducted the enquiry under Section 12(D) of the Tariff Commissions Act, 1950 and submitted its report in August 1968 (*vide* Tariff Commission's letter No. TC/ID/P-31/68, dated the 28th August, 1968).

2. The terms of reference to the Commission and the Summary of Recommendations and conclusions of the Commission are attached at Annexures I and II.

3. The 43 conclusions and recommendations of the Commission may be conveniently grouped together under the following 6 heads :

A. Cost structure of drugs and fair selling prices: Nos. 82 to 43.

B. Improvement in price control administration: Nos. 3 and 29.

C. Review and improvement of industrial licensing of drugs; 8, 9, 11, 12, 22 to 27.

D. Standards and quality of drugs and administration of the control law: 4 to 7, 10, 19, 20 and 28.

E. Imports and exports of drugs: 14, 15, 30 and 31.

F. General; 1, 2, 13, 16, 17, 18 and 21.

4.0. Government's decisions are as follows:—

A. *Cost structure of drugs and fair selling prices*

4.1. The prices of the following 17 drugs shall be as follows:—

	Prices to be Fixed by Government.
1. Vitamin A	Rs. 391·00/1000 mu
2. Vitamin C	Rs. 72·70/Kg.
3. Sulphadiazine	Rs. 58.89/Kg.
4 Tetracycline HCD	Rs. 850/Kg.
5. Chloroquin Phosphate	Rs. 259·53/Kg.
6. Streptomycin	Rs. 295/Kg.
7. Chloremphenicol	Rs. 357·66/Kg.
8. Amodiaquin	Rs. 106·91/Kg.
9. Chloropropamide	Rs. 95·60/Kg.
10. Tolbutamide	Rs. 74·16/Kg.
11. Prednisolone	Rs. 11,946·21/Kg.
12. I.N.H.	Rs. 126·16/Kg. if manufactured through indigenous picolines and Rs. 66·79/Kg. if manufactured through imported cyanopyridines).
13. P. A. S.	Rs. 31·28/Kg.
P. A. S. Acid	Rs. 41·83/Kg.
14. Iodochloro-Hydroxyquinolene	Rs. 65·68/Kg. (for production from basic stage) and Rs. 45·14/Kg. (for others).
15. Penicillin	
Potassium	Rs. 0·40/MU
Procaine	Rs. 0·50/MU
Sodium	Rs. 0·50/MU
Potassium V.	Rs. 0·80/MU
16. Tetanus Anti-toxin	Not to be fixed for the present. Price will be fixed when bulk supplies are made by the producers.
17. Vitamin B12	Rs. 100/gm.
18. Insulin	Rs. 4900/MU

4.2. As regards formulations, the Government have decided to bring the 49 formulations studied by the Commission as well as all other formulations within a system of price control the main features of which are

i) the prescription of a formula for price fixation, namely

$$RP=(MC+CC+PC)\times\left(\frac{(1+MU)}{100}\right)$$

where RP is retail price,

MC is materials cost and includes the cost of the basic drugs and pharmaceuticals aids;

CC is the conversion cost or the cost of formulation; PC is the packing charges and includes the cost of packing materials and packaging expenses; and

MU is the mark-up and is meant to cover forwarding charges, promotion expenses, after sales services and trade commission right up to the retail level.

(ii) the prescription of norms for determining the individual components of the formula;

(iii) the fixation of mark up, for arriving at retail prices, at 75 per cent of the manufacturers' cost, in the case of all existing ordinary drugs, a higher mark up of 100 per cent for a period of three years in respect of new products evolved as a result of special product development work and 150 per cent for a period of not more than five years in the case of new drugs which are products of original research containing new therapeutic ingredients within the meaning of clause 6(B) of Drug Prices (Display and Control) Order, 1966;

(iv) provision for a higher mark up in respect of formulations of non-essential bulk drugs (not being products of original research) not exceeding the ceiling of 150 per cent subject to the manufacturing units concerned observing certain procedure such as maintenance of separate accounts, etc. in order to encourage marketing of selected products of importance to the national health and well being, and promote exports, etc., while at the same time keeping the overall margin within the reasonable limit; and

(v) Opportunity to the industry to self-discipline itself in accordance with the above principles subject to Government's supervision and powers of refixation.

4.3. The margins for the trade shall be different for ethical drugs and non-ethical drugs as recommended by the Commission; 12 per cent for the retailer and 8 per cent for others in the case of ethical drugs and 10 per cent for retailers and 5 per cent for others in the case of non-ethical drugs, calculations being made on the basis of retail prices fixed as above.

4.4. A suitable Control Order incorporating the above points will be promulgated soon.

B. *Improvement in price control administration.*

5. It has been decided to strengthen and streamline the machinery dealing with price control administration. For this purpose a suitable Committee will be set up either in the Ministry of Petroleum & Chemicals & Mines & Metals or under the aegis of Bureau of Industrial Costs and Prices.

C. *Review and improvement of industrial Licensing of drugs.*

6. Licensing procedures will be tightened up with a view to remove the anomalies pointed out by the Commission. The circumstances in which excesses over licensed capacities have come into being will be investigated and regularised wherever necessary on condition that a reasonable portion of the benefits of the economies of scale inherent in larger capacities is made available to the society at large either through exports or lower prices.

D. *Standards and quality of drugs and administration of the control law.*

7. An effort is being made to evolve acceptable and convenient generic names.

E. *Imports and Exports of drugs.*

8. The Government agree that some system of pooling is desirable with a view to ensure the availability of raw materials and intermediates at the same rates for different manufacturers and that no unfair advantage accrues to a particular manufacturer or a group of manufacturers. Canalisation of the import of bulk drugs wherever possible is the accepted policy of the Government.

F. *General.*

9.0. Government do not accept the recommendations of the Commission on the banning of the use of capsules.

9.1. Government have noted the general recommendations Nos. 16, 17 & 21 and suitable action will be taken on them wherever possible.

10. In conclusion, Government places on record its appreciation of the work done by the Tariff Commission and the report submitted by it.

ORDER

Ordered that a copy of the resolution be published in the Gazette of India and a copy thereof communicated to all concerned.

ANNEXURE I

Terms of Reference

(1) To examine the cost structure of eighteen specified drugs and recommend to what extent the prices of the drugs can be lowered taking into consideration among other factors the following:

(a) Capital outlay including plant and machinery in relation to (i) actual production and (ii) potential capacity.

(b) Prices and quantities of raw materials and intermediates.

(c) Operation efficiencies of the processes.

(d) Allocation of direct overheads particularly large sums spent on advertisements, distribution of free samples, employment of highly paid salesman, sales promotion activities and other incentives.

(e) Prices at which similar products can be manufactured by small scale manufacturers who do not come within the purview of Industries (Development and Regulation) Act.

(f) To determine the prices at which the bulk drugs should be made available to other processers.

(2) To examine and recommend to what extent prices of essential formulations of the drugs specified can be reduced taking into account among other factors, the following:—

(a) Difference in prices of the formulations when sold under brand names and common names, and prices quoted against Government tenders and to the general public.

(b) Indirect elements such as management expenses, promotional expenses and sampling.

(c) Reasonableness of cost of containers, printing of labels, leaflets and other literature.

(d) Prices at which such formulations are sold by manufacturers to Government *vis-a-vis* the prices at which bulk drugs manufactured by them are sold to other formulators.

(e) To determine the reasonable relationship between ex-factory cost of a finished pre-paration and its consumer prices.

(f) Other factors mentioned under first terms of reference (1) which are relevant.

(3) To recommend the minimum and maximum Margins of profit covering all stages from the producer to the ultimate consumer.

(4) To recommend measures necessary to bring down the level of prices of basic drugs, pharmaceutical chemicals and intermediates and formulations of drugs

(5) To make any other recommendations which are considered relevant and which may have a bearing to bring about reduction in the cost of production and sale of drugs in India.

ANNEXURE II

Summary of conclusions and recommendations

Our conclusions and recommendations are summarised below :—

(1) Though the actual terms of reference relate to price reduction we have interpreted the reference in terms of the provisions of Section 12(d) of the Tariff Commission Act as an inquiry on prices of drugs.

(Paragraph 1.2)

(2) The scope of the inquiry covers (1) the 18 specified drugs sold in bulk; (2) single drug formulations of the specified drugs each containing any one of the specified drugs as its major therapeutic ingredient; and (3) multiple drug formulations of the specified drugs each containing two or more of the specified drugs only without addition of drugs outside the list.

(Paragraph 2.2)

(3) The difficulties mentioned by the Director, Drugs Control Administration, Maharashtra in the implementation of the Drugs Prices (Display and Control) Order, 1966 may be considered and suitable modifications introduced.

(Paragraphs 4.2.9 and 4.2.10)

(4) There ought to be uniformity of standards of administration, testing, approval and other matters regulating manufacture of drugs. Policies may be devised and implemented in such a way that the present disparity in these standards is removed.

(Paragraph 4.3.5)

(5) Steps may be taken both by Government and by the drugs and pharmaceuticals industry to arrive at uniform classifications and sub-classifications of the basic drugs. Information may be collected and published for these on uniform lines.

(Paragraph 6.1.4)

(6) Steps may be taken to ensure that State Drugs Controllers maintain records of the licences issued by them to manufacturers of drugs and these records should be readily available. It is also desirable that the list of such licences is published periodically on a Central basis for the whole country and it should contain the names of the units with location, year of grant of licence, drugs and formulations specified in the licence, installed capacity and annual production in terms of the quantity of formulations and drugs to be manufactured or suitable aggregates of the same.

(Paragraph 6.3.3)

(7) Even though there are more than 2,000 small scale units and each one functions under a licence, very little information is available in respect of their activities and contribution to the pharmaceutical industry. The State Drugs Controllers should collect information annually in respect of the small scale units on the lines indicated in paragraph 6.3.3.

(Paragraph 6.3.3)

(8) There are cases where the licensed capacities of units for manufacture of basic drugs are substantially higher than the capacities installed. While it is desirable to recognise the higher installed capacities where these have been established, it would be equally advisable to reduce licensed capacities where these have not been set up within the period stipulated for installation. This would be conducive to more healthy growth of the industry and would lead to

more scientific assessment of the requirements of the industry particularly in regard to foreign exchange and the size of other supporting industries producing raw materials.

(Paragraph 7.1.6)

(9) In the drugs and pharmaceuticals industry as in many other industries, on the one hand, quite a number of licences issued for installation and expansion have remained dormant, on the other, there are numerous cases where installed capacity has exceeded the licensed capacity and been permitted to so exceed with *ex-post-facto* approval in selected instances on the ground of increased production achieved and refusal in others. There is no uniform or firm policy at work in this regard. It would be opportune to make a thorough review of the working of the Industries (Development and Regulation) Act and the Rules and actual procedures adopted in granting the licences and approval or disapproval of changes in capacity from time to time.

(Paragraph 7.1.7)

(10) Suitable additions may be made to the Drugs and Cosmetics Rules for specifying the capacity of small scale units licensed or approved to manufacture basic drugs.

(Paragraph 7.1.8)

(11) The under-utilisation of capacity for the specified basic drugs does not reveal a healthy picture of the drugs industry. Extensive replanning is needed for achieving greater utilisation of capacities especially in the case of the units manufacturing the specified basic drugs.

(Paragraph 8.2.2)

(12) Steps need to be taken to ensure that the units licensed to manufacture basic drugs set up capacity within a stipulated period of time or the licence should be revoked. In the case of drugs which have to be imported owing to lack of adequate capacity, this principle should be enforced with greater vigour.

(Paragraph 9.4)

(13) Our estimates of consumption of the specified basic drugs for the years 1968, 1969 and 1970 are given in Table 11.4.

(Paragraph 11.5)

(14) For raw materials of which indigenous supplies are available, imports need to be discouraged, even if the cost of the imported material is lower than that of the indigenous one. Where the indigenous supply needs to be supplemented by partial imports, it would be desirable to ensure that some system of pooling is attempted so that the raw materials are available at the same rates to the different manufacturers and there is no unfair advantage to a particular manufacturer which is not available to the rest.

(Paragraph 12.1.5)

(15) It would be desirable to permit imports at concessional rates of customs duty in respect of specific raw materials and intermediates which are needed by the drugs and pharmaceuticals industry, until such time as indigenous capacities for such raw materials and intermediates are set up.

(Paragraph 12.1.5)

(16) A stage has now been reached when slaughter houses have to be used not only for providing meat as an item of food but also as sources of some of the important medicinal and biological raw materials. The States must therefore take in hand the regulation of large slaughter houses in such a way that the bye-products are not wasted but can be retrieved and utilised for medicinal and therapeutic purposes.

(Paragraph 12.2.8)

(17) The quality of materials like glass containers, rubber stoppers and aluminium strips and the lack of uniformity in size need the close attention not

only of the industry but also of Government and its various agencies which control and regulate production and quality in order to ensure that the indigenous industry is not found wanting even in those spheres where self-sufficiency is claimed but has not been achieved owing to lack of quality and conformity to specifications. Attention needs also to be paid very closely to the arrangements for raw materials and intermediates not produced by making their supply certain. Schedules need to be drawn up for this purpose in order to ensure that with a certain degree of vigilance of programme planning uncertainties are eliminated.

(Paragraph 12.2.8)

(18) It would be desirable to emulate the example of many advanced countries of Europe, particularly Denmark where no drugs in the form of capsules are marketed and drugs are sold in the form of tablets so that the use of imported Gelatine may be eliminated and foreign exchange saved.

(Paragraph 12.2.8)

(19) The existing legislation in our country recognises both generic names as well as brand names, but it is incumbent on the manufacturer to enter the generic name also prominently on the container. It would be desirable to revise generic names and introduce an abbreviated nomenclature for the purpose of drug manufacture with short, distinctive and easily spelt out names.

(Paragraph 13.25)

(20) Wherever preparations are prescribed in the form of combinations of two or more ingredients, it should be incumbent on the manufacturers who market such combinations to present to the Drugs Controller, Government of India, pharmacological and clinical data not only to prove the efficacy but also the superiority of such combinations over the straightforward preparations included in the pharmacopoeia or the National Formulary. When such clinical data are presented the manufacturer should also suggest a generic name for it which, if acceptable, would form a generic name for that product and if not acceptable, it may be open to the controlling authority to suggest an alternative generic name.

(Paragraph 13.26)

(21) The Patent Law is essentially meant to encourage inventions and in the national interest. Hence, all precautions need to be taken to see that patents which are granted in our country either in respect of indigenous or foreign inventions are not abused, *i.e.*, are not utilised to prevent further development.

(Paragraph 14.10)

(22) In the interests of saving of foreign exchange as well as possible economy of costs Parke-Davis, a manufacturer of the basic drug, Amodiaquin, should manufacture 4:7 dichloroquinoline from metachloro aniline, particularly when another unit with lesser facilities can do so and it should not therefore be allowed to import this intermediate. On the other hand, if it is not possible to do so, Bengal Immunity Co. should step up its production of 4:7 dichloroquinoline, so that it can meet the demand of other units also.

(Paragraph 15.7.1)

(23) It would be desirable for the other units producing the basic drug chlorpropamide to utilise the same process as adopted by Bengal Immunity Co. or alternatively a more efficient one or purchase locally produced intermediates.

(Paragraph 15.7.1)

(24) 8-hydroxyquinoline or dichloronitrobenzene needed for the manufacture of Iodo-chlor-hydroxy-quinoline should be produced locally.

(Paragraph 15.7.1)

(25) It is desirable to go into the reasons for the high cost of production of Vitamin-A by Glaxo Laboratories and if they are due to any process deficiencies, the unit should adopt the more efficient process of Roche Products.

(Paragraphs 15.7.2 and 28.2.2)

(26) Sarabhai Merck should pay serious attention to the reasons for the low yield of Vitamin-C obtained by it.

(Paragraph 15.7.3)

(27) It is relevant to consider whether manufacture of sulphadiazine involving a perpetual drain of foreign exchange for importing raw materials should be continued once the manufacture of sulphadimidine from predominantly indigenous raw materials is established.

(Paragraph 15.7.4)

(28) In order to have a more correct picture of the extent to which sub-standard drugs are being produced in the country it would be desirable to have analysis separately for generic as well as brand name products and also by units in the large scale as well as the small scale sectors.

(Paragraph 17.13)

(29) The anomalies pointed out by the manufacturers' associations in the procedures of Central and State Excise Authorities should be removed.

(Paragraph 19.4.4)

(30) Imports of basic drugs should always be related to the requirements of the country. Indian economy has not yet reached a stage and particularly in the chemical and pharmaceutical industries, where it can be exposed to competition from abroad or expected to establish its own market in the international field and compete at the level of international prices which in many cases are much lower than indigenous prices prevailing in the country of origin. This industry, like other Indian industries, has been enjoying protection in the form of quantitative restrictions of imports and if such protection is withdrawn all of a sudden and the industry is exposed to foreign competition, disastrous consequences are likely to ensue. These have been amply demonstrated during our inquiry for the 18 drugs, when in the case of not less than six items, the fall in the domestics production and setback to the industry has resulted from unplanned imports based on such estimates of production and demand, which were neither realistic nor helpful to the consolidation and development of the domestic units. Basic manufacture of drugs in the country has been established after considerable efforts and no steps should be taken which may retard the progress already made.

(Paragraph 20.7)

(31) Unless the costs of production of basic drugs are brought down drastically, it is not possible to build up any substantial exports, except at the cost of the internal market and by selling our products at less than half the cost.

(Paragraph 21.7)

(32) Sales promotion may be considered unobjectionable in the case of new drugs provided that no unsubstantiated claims are made but it should not be as relentless as it appears to be at the present moment in the case of already well established drugs and in any case the total expenditure on sales promotion should not exceed ten per cent of the ex-factory cost of the drug.

(Paragraph 22.2.4)

(33) The domestic prices of the selected drugs are generally very much lower in most cases in other countries.

(Paragraph 24.5)

(34) By and large, the prices in the Indian market of formulations compare favourably with the prices of similar formulations in the domestic markets of other countries.

(Paragraph 24.7)

(35) The price disparities of drugs sold under brand names and generic names are not because of these names but because of the units which manufacture them. Price differentials are in the present analysis more a factor of standing and size of the units than of the brand name itself.

(Paragraph 24.12)

(36) A commission of 25 per cent (15 per cent to the retailer and 10 per cent to other intermediaries) may be allowed for ethical drugs. The Commission allowed for non-ethical drugs may be 15 per cent, i.e., 10 per cent for the retailer and 5 per cent for other intermediaries.

(Paragraph 26.4)

(37) The sales turnover is roughly equivalent to the capital employed in the case of manufacturers of basic drugs, very much higher in the case of composite units and the highest for formulators only. Manufacture of basic drugs is a capital-intensive activity and the profitability is to be judged from the point of view of the capital employed. On the other hand, formulating activity by itself is not capital-intensive and profitability is related to the sales turnover since capital employed is about half of the amount of sales turnover.

(Paragraph 27.4.8)

(38) The fair ex-works selling prices recommended by us for the specified basic drugs are given in Table 28.2.

(Paragraph 28.20.1)

(39) The fair selling prices recommended by us for the selected essential formulations are given in Tables 29.2 and 29.3. Additional charges for dispensing tables and capsules in loose form may be allowed but no addition is needed in the case of vials, ampoules and tablet strips dispensed from larger packings.

(Paragraphs 29.9 and 29.10)

(40) The selling prices recommended by us for formulations are generally lower than the prevailing market prices, although in some cases these may appear to be high. Invariably in all such cases the present prices are based on imported materials the prices of which are lower than those of indigenous materials. The prices worked out by us appear therefore to be higher since those are based on indigenous raw materials. If such drugs continue to be formulated by using imported raw materials, the prices recommended by us would need to be revised.

(Paragraph 29.11)

(41) The element of excise duty has not been taken into account in fixing prices of single drug formulations sold under generic names or brand names, although excise duty is payable on formulations sold under brand names. We do not see any reason to distinguish between brand name and generic name formulations and hope that the use of brand names would be discouraged.

(Paragraph 29.12)

(42) Our findings on cost of production of basic drugs by small scale units are given in paragraph 30.2.

(Paragraph 30.2)

(43) Small scale formulating units do not afford any particular economy in comparison with those of the organised sector.

(Paragraph 30.4)

TABLE—28·2

Fair ex-works selling prices recommended for basic drugs

1. Vitamin A	Rs. 391·00 per 1000 m.u.
2. Vitamin B12	Rs. 113·84 per gm.
3. Vitamin C	Rs. 72·70 per kg.
4. Sulphadiazine	Rs. 58·89 per kg.
5. Penicillin Potassium G	Rs. 0·351 per m.u.
6. Sodium Penicillin G	Rs. 0·399 per m.u.
7. Procaine Penicillin	Rs. 0·336 per m.u.
8. Potassium Penicillin V	Rs. 0·357 per m.u.
9. Streptomycin	Rs. 285·00 per kg.

10. Chloramphenicol	Rs. 357·66 per kg.
11. Tetracycline	Rs. 709·25 per kg.
12. Amodiaquin	Rs. 106·91 per kg.
13. Chloroquin Phosphate	Rs. 259·53 per kg.
14. Iodo-Chlorohydroxy-quinoline	Rs. 45·14 per kg.
15. Chlorpropamide	Rs. 95·60 per kg.
16. Tolbutamide	Rs. 74·16 per kg.
17. Insulin	Rs. 5136·56 per m.u.
18. I.N.H.	Rs. 91·58 per kg.
19. P.A.S.	Rs. 31·28 per kg.
20. P.A.S. Acid	Rs. 41·83 per kg.
21. Tetanus Anti-toxin	No price fixed.
22. Prednisolone	Rs. 11,946,21 per kg.

B. MUKERJI, Secy.

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